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Note:

The surgery instructions outlined below reflect the surgery procedure usually chosen by the clinical consultant. However, each surgeon must decide individually which course of action offers the best chance of success in the individual case.



Introduction

EIN - Elastic Intramedullary Nails

The *Elastic Intramedullary Nail* can be adapted to the anatomical conditions and allows minimally invasive treatment. Treatment with the EIN requires only a small incision.

- The nail tip facilitates the insertion of the intramedullary nail and allows smooth sliding in the medullary cavity.
- The height of the curved tip ensures the correct relation to the medullary cavity.
- The nail tip facilitates manipulation of the nail for fracture reduction.
- 10 color coded diameters are available to cover the full range of indications.
- The titanium alloy (Ti6Al4V) combines excellent mechanical stability with elastic material properties.

Indication

- Treatment of diaphyseal and certain metaphyseal fractures of long bones in children
- Diaphyseal fractures of long tubular bone in upper extremity in adults
- Clavicle shaft fracture in adults



Surgical technique

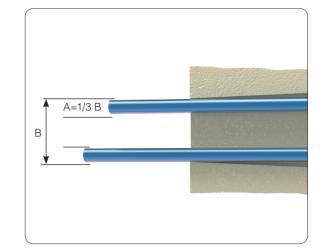
Femur – ascending technique

Determination of the nail diameter

- The narrowest point (isthmus) of the medullary cavity diameter is determined in the X-ray image.
- The diameter of an individual nail (A) should be 1/3 of the narrowest medullary cavity diameter (B).

Note:

• 2 nails of identical diameter must be selected in order to ensure that identical bending forces can oppose each other and prevent varus or valgus malalignment.



Pre-bending the nail

- In order to achieve good three-point support for the elastic nail in the femur, it is recommended that the part of the nail that is to be implanted is pre-bent to three times the medullary cavity diameter.
- The nails can be pre-bent by hand.
- Make sure that the nail is bent in the plane of the tip.
- The vertex of the arc should be on a level with the fracture zone.
- Pre-bend both nails in identical fashion.

Note:

• The nail should only be pre-bent in one direction. Bending back and forth several times will weaken the stability of the implant.

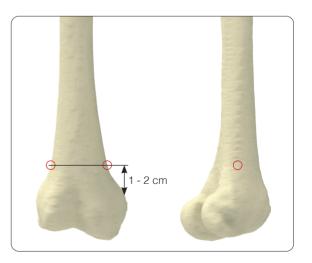
Determining the nail entry point

Incision

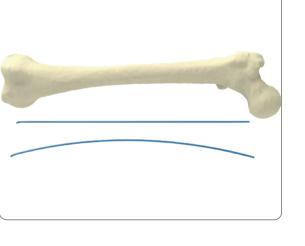
• Depending on the size of the child, a 2–4 cm incision is made on both the lateral and medial side of the femur at the planned opposing entry points.

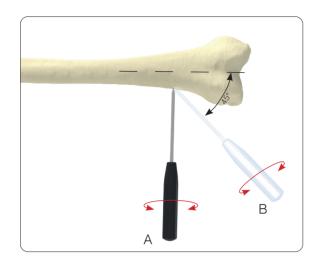
Nail entry points

• The nail entry points on the femur are located 1 to 2 cm proximal to the distal epiphyseal plate (on children approx. one finger width proximal to the upper pole of the patella).







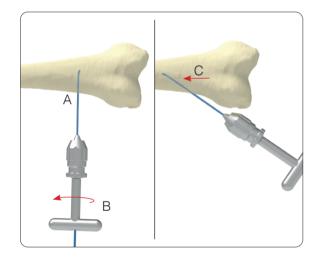


Opening the medullary cavity

Instruments

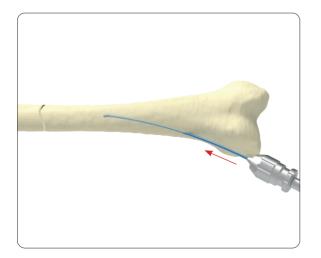
REF 09.20130.010 Awl for EIN Ø1.0mm up to Ø 5.0mm

- Adequately separate the fascia lata.
- Introduce the awl down to the bone at the upper end of the incision perpendicular to the shaft (A).
- Twist the awl to mark the bone.
- Then lower the awl to a degree of 45° to the shaft axis and bore through the bone under a twisting action (B).
- Repeat the process on the medial side.
- Check the location and depth of the awl in the X-ray image.



Insertion of the nails

- Clamp the first nail in the chuck.
- Align the nail tip at right angles to the femur shaft and insert the nail in the medullary cavity (A).
- Use the chuck to rotate the nail through 180° (B).
- Align the nail tip to the axis of the medullary cavity (C).



Sliding the nail forward

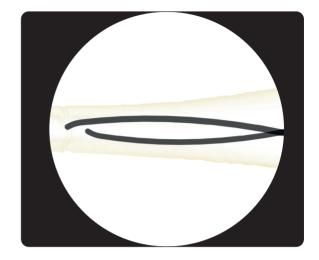
- Slide forward the first nail by hand under slight twisting motions until it reaches the fracture site.
- Make sure that the convex side of the nail tip slides along the inside of the cortex.

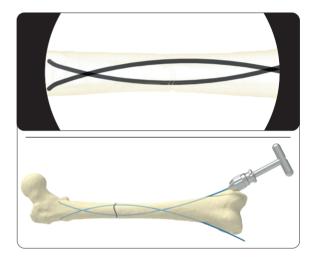


- At the contralateral entry point open the medullary cavity as described.
- Pre-bend the second nail with the same diameter (colourcoded) in the same way, insert it into the metaphysis and slide it forwards to the fracture site.
- Make sure that the second nail is distally and proximally in front of / behind the first nail.

Sliding the nails over the fracture site

- After alignment of the fracture fragments, both nails are pushed alternatingly under twisting over the fracture site.
- Afterwards the nails are pushed forwards to the metaphysis.
- In the proximal fragment, correctly align the nail tips to the medullary cavity in the frontal plane.
- Check the stability and rotation.
- After anchoring the nails in the metaphyses it is no longer possible to adjust the rotation.





Shortening the nails

Instruments

REF 09.20130.050

Cutter for EIN

• Once the nail tips are correctly positioned in the proximal fragment, both nails are shortened with the cutter to the required length.

Note:

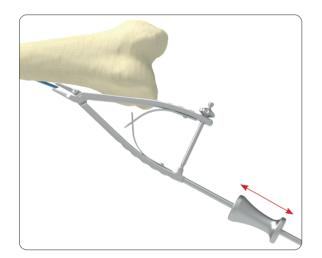
- Shorten the nails very close to the cortex.
- Over-long nails will cause formation of a pseudobursa and prevent free flexion of the knee.
- They can further also perforate the skin and cause infections.





Final positioning of the nail

• The inserted and shortened nails are driven into their planned anchoring position in the proximal metaphysis using light blows with the hammer.



Removal of implants

Instruments

REF 09.20130.040 REF 09.20130.145 REF 14.30060.146 Extraction Pliers for EIN Extractor for Nails Slide Hammer for Extractor

- Open the old incision and expose the nail ends.
- Grip the nail ends with the extraction pliers and bend them up so that there is no contact to the newly formed callus.
- Extract the nail by pulling strongly and twisting slightly at the same time.
- Alternatively, the extractor with slide hammer can be mounted on the extraction pliers to remove the nail with light hammer blows.



Femur – descending technique

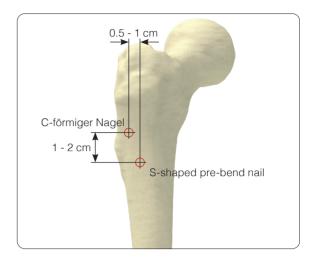
The monolateral descending technique is preferred for fractures of the distal third of the femur or of the distal metaphysis. The descending intramedullar nailing of the femur requires a different approach since both nails are inserted laterally.

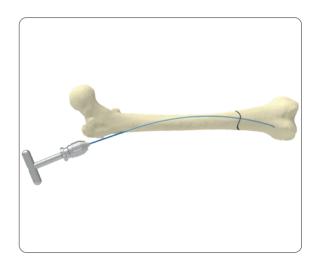
Incision

• Start immediately underneath the greater trochanter and extend to 3–4 cm distal, to just underneath the lesser trochanter.

Nail entry points

- As can be seen in the illustration, the nail entry points are subtrochanteric.
- The entry point for the C-shaped pre-bent nail is lateral.
- The entry point for the S-shaped pre-bent nail is anterolateral.
- The two entry points are separated by around 1–2 cm vertically and by around 0.5–1 cm horizontally.



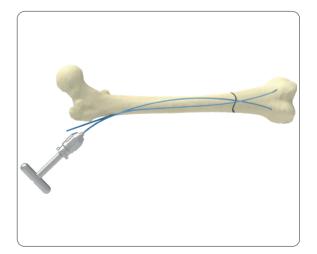


Insertion of the nails

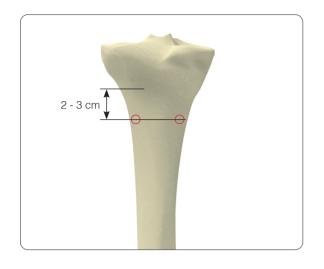
Instruments

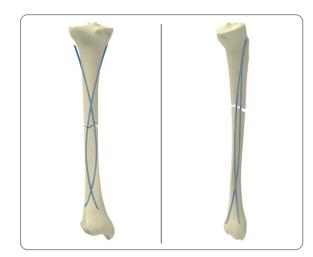
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REF 06.20050.045 Universal drill chuck
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- Insert the simple C-shaped bent nail via the proximal lateral entry point.
- Reposition the fracture with nail and establish primary stability.
- The second nail is initially pre-bent in a "C" shape in the first third, then inserted via the more distal anterolateral entry point until 2/3 of the nail is inserted to distal.
- Afterwards rotate the nail through 180°.
- Then bend the part of the nail that is still protruding from the cortex by approx. 90° to produce an "S" shape.
- After completed repositioning slide the nail forward into the distal fragment.









Tibia – descending technique

Tibia fractures should always be treated with the descending technique. 2 nails are normally required for the treatment of tibia fractures. These are inserted through one medial entry point and one lateral entry point into the proximal tibia. As already described above, isthmus of the medullary cavity diameter determines the diameter of the nail.

C-shaped pre-bending of the nails is recommended.

Incision

• Two symmetrical skin incisions of 2–3 cm are prepared proximally to the planned entry point, at the same level medially and laterally as the tibial tuberosity.

Nail entry points

• The entry points are positioned at the anterior at the proximal medial and at the proximal lateral metaphyseal cortex, 2 cm distal to the proximal epiphyseal plate, at the same level as the tibial tuberosity.

Note:

- Due to the triangular shape of the tibial medullary cavity, both nails have a tendency to drift in the dorsal direction, which would result in unwanted bending of the nails.
- Before the nails are driven into their final position in the distal metaphysis, the nail tips therefore need to be rotated slightly in the posterior direction in order to follow the physiological antecurvation of the tibia.
- On account of the very thin soft tissue mantle, both nail ends should be kept short and not bent upwards.



Forearm (radius and ulna)

Determination of the nail diameter

- The nail diameters are about 2/3 of the medullary isthmus of each bone.
- 2 nails with the same diameter must be chosen in order to prevent varus or valgus malalignments.

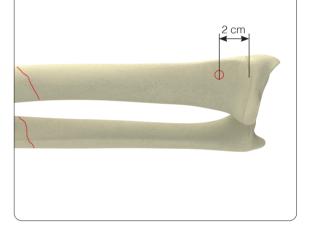
Determination of the nail entry point on the radius

Incision

- Access is gained dorsally via the dorsal tubercle of radius.
- The incision is normally made in the longitudinal direction.

Nail entry point

• The entry point at the radius is 2 cm proximal to the distal epiphyseal plate or, on an adult, 4 cm proximal to the joint line.



Determination of the nail entry point on the ulna

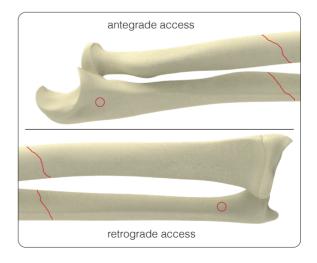
Incision

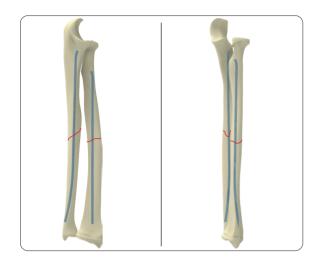
- For the antegrade access of a longitudinal incision on the dorsoradial side of the proximal ulna, start 3 cm distal to the apophysis.
- For the retrograde access, start the incision 3 cm proximal to the palpable ulnar styloid and extend it 2–3 cm in the distal direction.

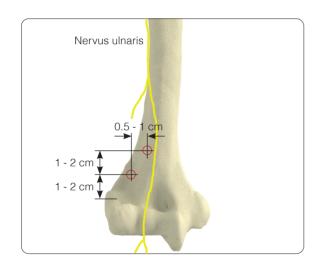
Nail entry point

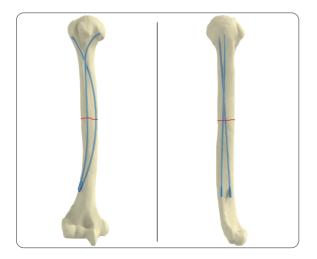
- For the antegrade technique, the entry point is on the anterolateral side of the proximal metaphysis, approx. 2 cm distal to the epiphyseal plate of the proximal ulna.
- For the retrograde technique, the entry point is on the anterolateral side of the distal metaphysis, approx. 2 cm proximal to the joint line.

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- As a general rule, only one nail is inserted into each bone for forearm fractures, as the radius and ulna form a unit together with the interosseous membrane of forearm.
- It is recommended that the nail is always placed in a retrograde approach in the radius to avoid the risk of damage to the deep branch of the radial nerve.
- The ulnar nail can be inserted either via the antegrade or via the retrograde access technique.

Note:

Advantage of retrograde access on the ulnar side:

- No change in position of the forearm required during reposition and nail insertion.
- Good visualisation is always possible with the aid of image intensifiers.

Humerus - ascending technique

The monolateral ascending technique is applied to fractures of the proximal humerus and the humeral stem. Here, 2 nails are inserted with the retrograde technique on the anterolateral (radial) aspect of the distal humerus. Ulnar access should be avoided due to the risks to the ulnar nerve.

Incision

• Start the incision around 1 cm above the palpable lateral epicondyle and extend it 3–4 cm in the proximal direction in order to outline the lateral aspect of the humerus.

Nail entry points

• The entry points are located at the supracondylar lateral ventral aspect outside of the capsule.

Note:

• Always pay close attention to the position of the radial nerve in relation to the fracture.



Humerus – descending technique

The monolateral descending technique is applied to fractures of the distal humerus, including supracondylar fractures of the distal humerus.

Incision

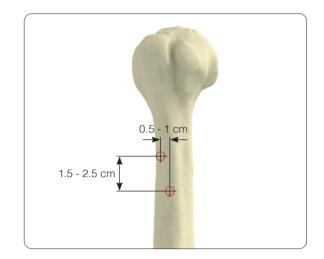
• Make an incision 3–4 cm proximal to the planned entry point. Then outline the humerus subperiosteally.

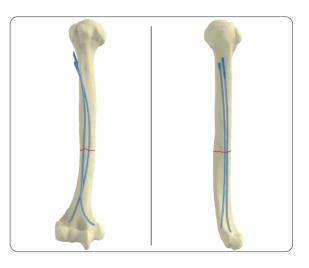
Nail entry points

• The entry points are positioned laterally and distally of the deltoid tuberosity. A more distally positioned entry point could endanger the radial nerve.

Note:

• Always pay close attention to the position of the radial nerve in relation to the fracture.



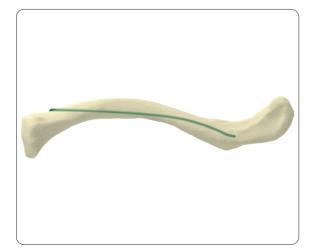




Clavicle

- Thanks to its elasticity, EIN nails are suitable for the treatment of clavicle fractures.
- The nail adapts to the anatomical conditions and enables minimally invasive treatment.
- The treatment with an EIN nail requires only a small incision.
- Noticeable pain relief and optimum restoration of function can be achieved.





- The elastic nail is usually inserted via the medial access in the lateral direction into the clavicle.
- In comparison to lateral access, access from the medial side enables better identification of the medial aspect of the clavicle and facilitates handling.
- In addition, with medial access there is a lower risk of injury to the central vessels.

Incision

• Above the medial aspect of the clavicle make a 1 - 1.5 cm long incision in the direction toward the main cleavage line (Langer line).

Nail entry point

- The entry point is 1 2 cm distal to the sternoclavicular joint centrally in the anterior quadrant of the medial clavicle.
- In this region the formation of the cortical structures is weaker, and the cortex is thinner.



Product information

Assembly of the Cutter

Instruments

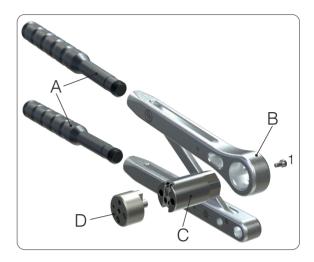
 REF 09.20130.050
 Cutter for EIN

 REF 09.20130.050-6
 Handle

- Both handles (A) are screwed into the cutter and hand-tightened.
- When assembling the cutter, part C must first be inserted in part B.
- Subsequently, part C is screwed with part B via the screw 1 (hex 2.5mm).
- In the next step part D is put on part C.
- Next, part E is pushed over part C and part D.
- With the screw 2 (hex 5.0mm), part E is screwed to the handle.

• Part F is inserted in the last step on Part E and screwed with

the screws 3 (hex 2.5mm) and 4 (hex 5.0mm).







Disassembly of the Cutter

Instruments

 REF 09.20130.050
 Cutter for EIN

 REF 09.20130.050-6
 Handle

• The disassembling of the cutter takes place in the reverse order as the assembly described above.



Implants

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EIN - Elastic Intramedullary Nail

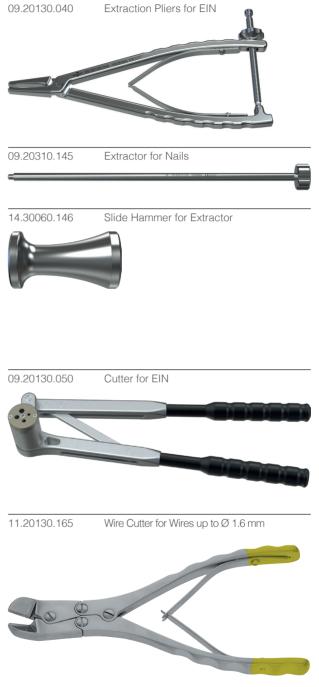
Article Number *	Nail diameter	Length (mm)	Color	
09.31010.100	1.0 mm	100	gold	
09.31014.100	1.4 mm	100	red	
09.31015.300	1.5 mm	300	red	
09.31020.450	2.0 mm	440	green	
09.31025.450	2.5 mm	440	red	
09.31030.450	3.0 mm	440	gold	
09.31035.450	3.5 mm	440	blue	
09.31040.450	4.0 mm	440	purple	
09.31045.450	4.5 mm	440	grey	
09.31050.450	5.0 mm	440	titanium	

* All implants are also available in sterile. Therefor, add suffix "S" to article number.



Instruments









MRI Safety Information

Non-clinical testing has demonstrated that the Intramedullary Nails range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B₀)
 - Spatial field gradient lower than or equal to
 - 1.5 T: 23.45 T/m (2345 G/cm)
 - 3.0 T: 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
 - RF excitation: Circularly Polarized (CP)
 - RF transmit coil: whole-body transmit coil
 - RF receive coil type: whole-body receive coil
 - Maximum permitted whole-body averaged specific absorption rate (SAR):
 - Normal Operating Mode, 2 W/kg.
 - Scan duration and wait time:

1.5 T: 2 W/kg whole-body average SAR for **10min and 55s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **10min and 55s** if this limit is reached.

3.0 T: 2 W/kg whole-body average SAR for **7min and 54s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **7min and 54s** if this limit is reached.

- The Intramedullary Nails are expected to produce a maximum temperature rise of 6.2 °C at 1.5 T and 6.5 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 83 mm from the device edge when imaged with a spin echo pulse sequence and 65 mm with a gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

Note:

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.





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